Finally, the Deputy Administrator agrees with Judge Tenney's finding as to the relevancy of the Respondent's testimony before him concerning the cocaine incident and factor five, ''other conduct which may threaten the public health or safety.'' Specifically, the Deputy Administrator finds that the Respondent's lack of candor in his 1994 testimony as to the full extent of his involvement in the cocaine incident creates concern about his future conduct. The record discloses that the Respondent was quite involved in the cocaine distribution and conspiracy, as evidenced by the stipulated testimony of the undercover Agent involved first-hand in the incident, and by the fact that the Respondent pled guilty to the charges of conspiracy to distribute cocaine and unlawfully distributing cocaine. His failure to take responsibility for his past misconduct causes concern about his commitment to protecting the ''public health and safety'' in the future, should he be granted a DEA Certificate of Registration.

However, the Government's establishment of its case does not end the inquiry, for the Respondent has submitted extensive evidence of his rehabilitative efforts. The issue then becomes whether the Respondent has offered sufficient proof of rehabilitation to mitigate the egregious conduct established by the Government, such that the DEA can now find that granting the Respondent's application for a Certificate of Registration would be consistent with the ''public interest.'' See *Shatz* v. *United States Dept. of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989) (holding that, in a case such as this, the Respondent has the burden to prove rehabilitation).

Again, the Deputy Administrator agrees with Judge Tenny's findings as to the weight to be given the Respondent's rehabilitative evidence, for the Respondent's evidence concerning his rehabilitative efforts, to include his commitment to performing good deeds through a variety of Christian ministries, was credible. However, the Respondent's November 1994 testimony concerning his conduct surrounding the May 1, 1986, cocaine transaction was indeed troubling, for despite the plea and conviction, the Respondent continued to minimize his involvement and resulting responsibility for the conspiracy and cocaine distribution incidents. As Judge Tenny noted, ''the Respondent's inability to be completely candid at the hearing causes sufficient doubt as to whether he is fully rehabilitated.'' Further, the Deputy Administrator also notes the lack of evidence of continuing education relevant to controlled substances, evidence which would have been helpful in light of the Respondent's experience in prescribing Didrex without understanding its characteristics.

Therefore, the preponderance of the evidence supports denial of the Respondent's application at this time. If the Respondent reapplies and submits evidence of his continuing rehabilitative efforts, such as evidence of completion of educational courses at least partially focused upon the handling of controlled substances, then his application may receive more favorable consideration. See, e.g., *Shatz*, 873 F.2d at 1092 (suggesting that ''careful consideration'' be given to any future application for registration, and in particular, to ''any additional evidence in support of [a] claim of rehabilitation''); *Sokoloff* v. *Saxbe*, 501 F.2d 571, 576 (2d Cir. 1974) (stating that ''permanent revocation'' of a DEA Certificate of Registration may be ''unduly harsh'')

Therefore, the Deputy Administrator finds that the public interest is best served by denying the Respondent's application at this time. Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823, and 21 C.F.R. 0.100(b) and 0.104, hereby orders that the Respondent's application for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective January 8, 1996.

Dated: November 30, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–29771 Filed 12–6–95; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 93–39]

William F. Skinner, M.D., Continuation of Registration

On April 5, 1993, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to William F. Skinner, M.D., (Respondent) of Santa Monica, California, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AS7287534, under 21 U.S.C. 824(a)(4), and deny any pending applications under 823(f), as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged that:

(1) During the period April 1987 through November 1988, the Respondent prescribed, administered, and dispensed excessive amounts of controlled substances to a single patient, including Demerol, Dilaudid, Xanax, Ativan, Percodan, Tylenol with Codeine, Valium, Percocet, Methadone, and Doriden, without a legitimate medical purpose and while not acting in the usual course of professional practice; and

(2) During the same time period, the Respondent prescribed narcotic drugs to the same narcotic dependent patient for the purpose of maintenance treatment, and engaged in detoxification treatment of the patient without holding a separate DEA registration to conduct a narcotic treatment program.

On April 27, 1993, the Respondent, through counsel, filed a timely request for a hearing. On February 23, 1994, the case was consolidated for hearing with *Michael S. Gottlieb, M.D.*, Docket No. 93–53, and *Michael J. Roth, M.D.*, Docket No. 94–10. Following prehearing procedures, a hearing was held in Los Angeles, California, on March 29–30 and May 10–12, 1994, before Administrative Law Judge Paul A. Tenney. At the hearing, both parties called witnesses to testify and introduced documentary evidence, and after the hearing, counsel for both sides submitted proposed findings of fact, conclusions of law and argument. On October 17, 1994, Judge Tenney issued his Findings of Fact, Conclusions of Law, and Recommended Ruling, finding that Respondent's registration was not inconsistent with the public interest, and recommending that no action be taken against Respondent, Dr. Skinner. On November 8, 1994, the Government filed exceptions to Judge Tenney's opinion, and on December 7, 1994, the Respondent filed his response to the Government's exceptions. On December 12, 1994, Judge Tenney transmitted the record of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the filings of the parties and the record in its entirety, and pursuant to 21 C.F.R. 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the opinion and recommended ruling of Judge Tenney, and his adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law.

The Deputy Administrator finds that the Respondent is licensed to practice as a physician in the State of California, and that he had served as the medical director of the St. John's Hospital Chemical Dependency Center from 1981

to 1990. He is registered with the DEA as a practitioner authorized to handle controlled substances in Schedule II through V.

The DEA's allegations concern the Respondent's treatment of one patient, ''Patient A'', from March 1986 through October 1988. During this time period, Patient A had a number of significant physical conditions which caused pain, including pressure on the nerves from cervical degenerative joint disease; degenerative osteoarthritis of the lumbar vertebrae above a previous area where fusion surgery had been performed; spinal stenosis which occurs when the spinal canal narrows, at times putting pressure on a nerve with pain and muscle spasms; severe temporal mandibular joint degenerative disease; compression fracture of the patient's spine at L–1 and L–2; and trochanteric bursitis of the hip. Also during this time period, Patient A had a series of accidents which caused her acute pain: An automobile accident in which she was a passenger, resulting in a whiplash injury to her neck; an accident resulting in a knee injury; a fall down a spiral staircase, resulting in back strain; and a fall on a marble floor, resulting in a compression fracture of her spine. The record contains no evidence that drug intoxication caused any of these accidents.

During the time period of March 1986 through October 1988, the Government contended that the Respondent prescribed controlled substances to Patient A for other than a legitimate medical purpose and not in the usual course of his professional practice. Beginning March 20, 1986, the Respondent prescribed Demerol to Patient A. Demerol is a brand name for a medication containing meperidine hydrochloride, a Schedule II controlled substance. During the remainder of 1986, the Respondent prescribed Demerol and Percodan or Percocet, and occasionally he prescribed other Schedule II substances, such as Dilaudid, Doriden, and Tuinal. For example, from May 13 through December 26, 1986, the Respondent prescribed 1,604 tablets of Percodan or Percocet, and from March 20 through December 26, 1986, he prescribed approximately 30,000 milligrams of Demerol. This prescription practice continued into 1987 and 1988. However, also as a part of his prescription pattern, the Respondent tapered the amount of narcotics prescribed after the incidents of acute pain following the injuries suffered as a result of the various accidents. Dr. Smith, Dr. Ling, and Dr. Margoles testified that such tapering was within the usual course of professional practice.

Also throughout this time period, the Respondent used various non-narcotic methods of treating Patient A's pain. Specifically, he ordered bed rest, traction, hot packs, ultrasound, steroids, biofeedback, massage, electrocane, a cervical collar, facet blocks, physical therapy, acupuncture, and non-narcotic drugs. The Respondent also referred Patient A to numerous specialists, including Dr. Dodge, a neurosurgeon, Dr. Horacek, an orthopedic surgeon, and Dr. Woods, a neurologist.

However, Dr. Skinner was the primary treating physician for Patient A, and his treatment records were included in the record of this case. The medical records recounted the Respondent's observations, examination results, and the prescriptions issued as a result of his house calls to Patient A. Further, the medical records also contain hospital test results, hospital admission, treatment and discharge records, and consultation reports. For example, the medical records show that Patient A was hospitalized during this time period. On July 26, 1988, following a CAT scan, Dr. Joyce issued a report, writing that Patient A had a mild compression fracture at L1, mild stenosis at L2–3, moderate stenosis at L3–4, and a post-posterior bony fusion from L4 to the sacrum. Patient A was discharged on August 18, 1988. Again on September 29, 1988, Patient A was admitted to the hospital by Dr. Skinner, and she was discharged on October 4, 1988, with a diagnosis of a compression fracture, osteoporosis, and congenital scoliosis. On October 17, 1988, Patient A was again admitted with a complaint of severe left leg pain, and on October 23, 1988, she was discharged with the diagnosis of acute back pain secondary compression fracture of L1, acute lumbosacral spinal sprain and strain secondary to severe osteoarthritis at L2–3 with neuroforaminal narrowing, sciatica (resolved) and osteoporosis with high risk of possible spontaneous hip fracture.

Further, as Judge Tenney noted, ''[t]here is a 'debate' or difference of opinion between those [physicians who] specialized in addiction medicine and those in pain management regarding the use of narcotics for the treatment of severe pain.'' He also noted that Dr. Smith and Dr. Ling, the Government expert witnesses, were primarily experts in addiction medicine, and Dr. Margoles and Dr. Brechner, the Respondent's expert witnesses, were primarily experts in pain management. Dr. Smith and Dr. Margoles agreed that there exists a difference of opinion within the medical community as to the appropriate level of prescribing of controlled substances for the treatment of chronic pain patients. Also significant is the fact that the opinions of Dr. Brechner, Dr. Dodge, Dr. Horacek, and Dr. Woods were supported by either their personal examination, treatment, or both, of Patient A during the relevant time period, whereas the opinions of Dr. Smith and Dr. Ling were based upon their review of Patient A's treatment records and prescription documentation.

Initially, the Government presented evidence from expert witnesses who had concluded that Patient A was addicted to controlled substances, and that the Respondent had prescribed medications to Patient A to maintain her addiction. On March 3, 1990, Dr. Smith wrote in a report for the District Attorney: ''[the] spectrum of medications [prescribed to Patient A] was not justified by the medical pathology and, in fact, the medications caused the patient far more harm than benefit. The dosage of medication was clearly excessive and the duration over the several month period as outlined in the medical records was both excessive and not justified by the medical pathology.'' He concluded that ''[a]s a result of this analysis it is my opinion then, that Dr. Skinner and his colleagues were not prescribing a narcotic medication primarily for the management of pain but, in fact, were maintaining her addiction.'' During the hearing before Judge Tenney, Dr. Smith, after reviewing the quantities of controlled substances prescribed on selected dates, testified that those quantities were excessive in light of the standard therapeutic dosage. He then restated the conclusion he had reached in his 1990 letter to the District Attorney.

Based upon his review of Patient A's treatment record and relevant pharmacy records, Dr. Ling, a medical expert in the areas of neurology, psychiatry, addiction, and pain medicine, opined that the Respondent's prescribing practices did not meet the standard of care of the average practitioner with experience in the field of chemical dependency. He also testified that, in 1988, the standard of care was not to prescribe a large amount of narcotics, for such practice could result in the patient's developing a tolerance to controlled substances. He testified: ''You'd be treating the tolerance. You'd be treating addiction, you're no longer treating the [diagnosed medical condition].''

Both Dr. Smith and Dr. Ling concluded that Patient A was an addict who was opiate dependent and

benzodiazipine dependent. However, Dr. Ling also testified that he believed a drug dependent patient was entitled to treatment for pain, that Patient A was in pain, and that the Respondent was treating her in good faith.

The Respondent presented evidence from consulting physicians who had concluded that Patient A was not an addict, but that she was dependent upon controlled substances for treatment of her chronic and sometimes acute pain. Specifically, Dr. Margoles, a medical expert in pain management, testified, after having reviewed Patient A's medical history and having interviewed her twice, that throughout the years 1986 to 1988, Patient A had experienced intractable pain as a result of numerous medical problems and degenerative changes. He concluded that Patient A was a chronic pain patient, as opposed to an opioid abuser, and that she sought and was given medications to control her pain, not for euphoria. He found that, although Patient A had received an increase in amounts of opioids prescribed for her use, such an increase had resulted from the severity of her pain, not from addiction. He testified: ''It was obvious that the medication was being used to keep her going in her professional career.'' He also summarized the distinction between the use of pain medication to enable a patient with pain to function, and the use of narcotics to simply maintain an addict, as follows: ''the chronic pain patient * * * [is] goal oriented, they're working, they're functioning. They've got something in mind, they've got a goal. They're working, they've got a job. Narcotic maintenance is usually, as far as I'm concerned, * * * just keeping a person * * * from going through withdrawal symptoms.'' Also, he noted that there was no evidence in Patient A's records of abstinent syndrome, clinical or laboratory evidence of toxicity, nor evidence that she had sought drugs in order to obtain euphoria. Dr. Margoles testified that the lack of toxicity evidence meant that the ''patient obviously tolerated the medication that she had, that was used in her case, and evidently benefitted her [,] and [that] she had no toxic side effects * * * no slurred speech, inability to have cognitive speech, straight speaking.''

Finally, Dr. Margoles noted that in the 1980's, guidelines were established in prescribing controlled substances for chronic conditions. These guidelines were indorsed by various medical and legal groups, to include the California Board of Medical Quality Assurance and the California Bureau of Narcotic Enforcement. Dr. Margoles testified that the Respondent's prescribing to Patient A met these standards.

The Respondent also presented an affidavit from Dr. Dodge, a consulting neurosurgeon involved with the treatment of Patient A from 1986 through 1988, who wrote:

> In my opinion, although the amounts of drugs were large compared to the average patient, they were necessary in order to treat the patient's pain. Although the patient clearly had a drug dependence problem, I do not believe the pain was controllable by other means besides narcotics. The amounts of narcotics tended to increase at the time of the acute events * * *. Dr. Skinner and the other physicians responsible for her care always attempted to minimize the amounts of drugs that she took and sought to detoxify her from those drugs when the acute phase of pain and muscle spasm from the injuries passed.
>
> In my opinion, Dr. Skinner and the other physicians responsible for her care did not violate the standard of practice in prescribing narcotic analgesics to this patient.

Further, is an affidavit, Dr. Woods, a neurologist who treated Patient A from January 1987 to January 1988, made similar observations as Dr. Dodge, and concluded: ''In my opinion, Dr. Skinner and the other physicians responsible for her care did not violate the standard of practice in prescribing narcotic analgesics to this patient, in that the drugs were prescribed to control the patient's pain not to maintain her addiction.''

As to the legitimacy of the quantities of the controlled substances prescribed, Dr. Brechner, a medical expert in the field of pain management and anesthesiology, testified that in 1988, he was consulted concerning an aspect of Patient A's treatment, for he had performed a facet block procedure to aid in the diagnosis of the source of Patient A's back pain. In the course of performing that procedure, he administered narcotic analgesics, observing that Patient A had ''an extraordinary tolerance to narcotics, even when potentiated with the tranquilizers.'' Dr. Brechner also noted that Patient A suffered from severe chronic pain and from periods of acute, intractable pain. Dr. Brechner concluded that Patient A had received narcotics prescribed in amounts that were ''extraordinary compared to the average patient,'' because of her extreme tolerance for narcotics, and that she needed the narcotics in the amounts prescribed in order to control her pain. He testified that prescribing the narcotics in lower doses was not effective, and thus, she was not ''over-dosed.'' Also, Dr. Brechner testified that alternative means of treatment were tried to control Patient A's pain, but that he did not believe such treatment was effective alone in treating the pain resulting from her acute pain-inducing incidents, such as the automobile accident or the fall down the stairway. Finally, Dr. Brechner testified that the doctors treating Patient A prescribed narcotics for a legitimate medical purpose, to treat her pain, and not to maintain her condition as an addict.

Also, the Respondent testified that he had begun treating Patient A at the request of Dr. Roth in 1983. Dr. Skinner testified extensively about the acute pain incidents experienced by Patient A through 1988, the consulting physicians' diagnoses resulting from these incidents, and the various narcotic and non-narcotic treatment regimen implemented to control her pain. He also stated that there was no evidence that drug intoxication caused any of Patient A's acute events, and that he had made an extra effort to insure her lack of toxicity throughout his treatment of her. Further, Dr. Skinner testified that all narcotics were either administered in the hospital or under the supervision of a private duty nurse selected by him from the nursing staff of the Chemical Dependency Center at Saint John's Hospital, and that the nurses were familiar with Patient A's case, her tolerances, and with treating patients who had Patient A's type of problems. As a result of his treatment of Patient A, Dr. Skinner concluded that she was not an addict: ''She did not demonstrate typical findings of addiction behavior * * * never did she evidence toxicity, never did she evidence any abstinence withdrawal syndrome, and never did she evidence, while under my care at home or in the hospitals, any evidence of street-like drug seeking behavior.'' He also stated that, given Patient A's medical condition, he did not believe that he over-prescribed controlled substances to her. Further, he testified that in prescribing medications to Patient A, he would taper her off the medicines to try to control her tolerance levels. He strongly denied prescribing controlled substances to Patient A to maintain an addiction, stating: ''if it [is] your contention that I was maintaining an addict, what motive would I possibly have for that? It's against all the training that I have; it's against everything that I have done in treating chemical dependency patients.''

Also, as to the Respondent's recordkeeping practices, he testified that he was aware that tabloid newspapers would pay clerks at the hospital to copy celebrity patient records, such as Patient A's, and to send the records to the tabloids. Therefore, the Respondent stated he was careful in his records to document conditions and prescriptions

made to Patient A, while remaining in compliance with federal laws of confidentiality.

As to his future practice, the Respondent stated that if he encountered a medically complex patient similar to Patient A, he would refer that patient to a chronic pain management specialist. He also testified concerning his current practice and the need for his DEA Certificate of Registration.

Pursuant to 21 U.S.C. 824(a)(4) and 823(f), the Deputy Administrator may revoke or suspend the Respondent's DEA Certificate of Registration and deny any pending application for such registration, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. See *Henry J. Schwarz, Jr., M.D.*, Docket No. 88-42, 54 FR 16422 (1989).

In this case, factors two, four, and five are relevant in determining whether the Respondent's continued registration would be inconsistent with the public interest. As to factor two, the Respondent's ''experience in dispensing * * * controlled substances,'' and factor four, the Respondent's compliance with ''Federal, State, or local law,'' the Government contends that during March 1986 through October 1988, the Respondent prescribed controlled substances in the treatment of Patient A not for a legitimate medical purpose and not in the usual course of his professional practice, in violation of State and Federal law. Specifically, the Government argues that controlled substances were prescribed to Patient A during these periods to maintain her addiction, and that the amount of narcotics prescribed far exceeded what Patient A needed for pain relief.

An ''addict'' is defined in 21 U.S.C. 802(1) as ''any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to [one's] addiction.'' There was no dispute that very high does of narcotic analgesics were administered to Patient A, but the evidence also demonstrated that she had a high tolerance to the controlled substances and required this dosage to effectively treat her pain. Patient A's medical records and the statements and testimony of medical experts established that Patient A had several injuries and was plausibly experiencing severe and chronic pain.

Further, the evidence did not adequately establish that Patient A was an ''addict.'' No evidence was presented to show that Patient A had acted to ''endanger the public morals, health, safety, or welfare,'' or that she had a compulsion to use drugs, had lost control over the drugs, or that she continued to use the drugs in spite of adverse consequences. Also, medical testimony was presented to establish that, although considered, there was no evidence of abstinent syndrome, slurred speech, inability to have cognitive speech, nor clinical or laboratory evidence of toxicity. However, there was expert testimony to establish that use of the controlled substances helped Patient A to function and participate in her professional activities in spite of chronic pain. Although the Respondent did not deny that Patient A had experienced chemical dependency for the control of her pain, he did testify that he was not prescribing controlled substances to Patient A to maintain an addiction, for she had not presented any addictive behavior to him. Therefore, the Deputy Administrator concurs with Judge Tenney's finding that the ''preponderance of the evidence demonstrates that although Patient A was prescribed a large amount of controlled substances, these were prescribed by Dr. Skinner for a legitimate medical purpose and in the usual course of his professional practice.''

The Government also asserted that the Respondent's practices violated California Health and Safety Code Sections 11153 and 11154. Pursuant to Section 11153(a), a ''prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice,'' and a prescription issued ''for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment * * * but for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use'' would not be a legal prescription pursuant to this section. Section 11154 provides in relevant part that ''[e]xcept in the regular practice of his or her profession, no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person * * * which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance * * * .''

The Respondent asserted that he had prescribed controlled substances to Patient A in good faith, and that such prescribing was an absolute defense to an allegation of violation of these State law provisions. Dr. Ling testified that he accepted that the Respondent believed Patient A was in pain, and that he was treating her in good faith. Dr. Margoles also testified to the Respondent's good faith treatment of Patient A.

The Deputy Administrator agrees with the conclusion of Judge Tenney, that the Respondent did not violate these State code provisions. See *People* v. *Lonergan*, 219 Cal. App. 3d 82, 90 (1990) (acting in ''good faith,'' as defined by California Health and Safety Code 11210, exempts a physician from criminal liability under the provision of 11153). In response to the Government's exceptions relevant to the standard applicable in this administrative proceeding, the Deputy Administrator also finds that the preponderance of the evidence was against a finding that Patient A was an ''addict'', and supports the conclusion that the Respondent had prescribed controlled substances to Patient A for a legitimate medical purpose, treating her pain, while acting in the usual course of his professional practice. Thus, the evidence does not support a finding that the Respondent violated the cited State law.

Next, the Government asserted that from April 1987 through November 1988, the Respondent performed detoxification or maintenance treatment of a narcotic drug-dependent patient without obtaining a registration for that purpose, in violation of Federal law. Pursuant to 21 U.S.C. 802(30), ''detoxification treatment'' is—

> the dispensing for a period not in excess of one hundred and eighty days of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal

from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

Further, the statute defines ''maintenance treatment'' as the dispensing, ''for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.'' 21 U.S.C. 802(29). However, the applicable implementing regulation states in pertinent part:

> This section is not intended to impose any limitations on a physician * * * to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or * * * to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

21 CFR 1306.07(c).

The preponderance of the evidence supports a finding that the Respondent was tapering the drugs prescribed to Patient A after acute pain resolved. Dr. Ling, as well as others, testified that such tapering would be appropriate under such circumstances. Further, the record does not establish that Patient A experienced ''adverse physiological or psychological effects incident to withdrawal'' nor that, in fact, Patient A exhibited behavior consistent with the finding that she was an ''addict.'' Therefore, the Deputy Administrator agrees with Judge Tenney, that the ''Respondent made a reasonable effort to manage the patient's intractable pain and limit the patient's use of controlled substances in terms of treatment of [Patient A's] other medical conditions, and did not prescribe controlled substances to her primarily to wean her from dependence on narcotic analgesics.'' Thus, the Respondent was not maintaining Patient A's addiction nor detoxifying Patient A without a prior registration.

Finally, the Government argued that from March 1986 through October 1988, the Respondent failed to keep adequate medical records of his treatment of Patient A, and thus, his prescriptions were not issued for a legitimate medical purpose nor in the usual course of professional practice in violation of 21 CFR 1306.04, and California Health and Safety Code Sections 11168, 11190, and 11191. Yet the Government failed to cite to any specific inadequacies of the Respondent's records in either their proposed findings of fact or in the exceptions filed to the Administrative Law Judge's recommended decision.

Pursuant to 21 CFR 1304.03(c), a ''registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.'' Further, a ''registered individual practitioner is not required to keep records of controlled substances listed in [Schedules II through V] which are administered in the lawful course of professional practice unless the practitioner regularly engaged in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered.'' 21 CFR 1304.03(d). Here, the Respondent prescribed controlled substances to Patient A, but the record does not indicate that he ''regularly dispensed'' those substances to her nor that he prescribed them ''in the course of maintenance or detoxification treatment.'' The Deputy Administrator thus agrees with Judge Tenney's conclusion that ''the Government failed to prove that Respondent kept inadequate records. No violation of the Federal statute is found.''

As for violations of State law, California Health and Safety Code Section 11190 provides that a practitioner who issues a prescription of a controlled substance classified in Schedule II must make a record for each transaction which shows the name and address of the patient, the date of the transaction, the ''character, including the name and strength, and quantity of controlled substances involved'', and the pathology and purpose for which the prescription was issued. The Government did not cite to any specific instances where the Respondent failed to provide this required information. Thus, after reviewing the record, the Deputy Administrator agrees with Judge Tenney's conclusion that the ''DEA did not prove that there were recordkeeping violations by a preponderance of the evidence.''

As to factor five, ''such other conduct which may threaten the public health and safety,'' the Government argued that the Respondent's pattern of prescribing to Patient A caused a threat to the public health and safety. As Judge Tenney noted, this is an unusual case for it involved the Respondent's prescribing practices for a single patient, and no evidence was provided to show a pattern of excessive prescribing to any other patients. Further, as to that single patient, the Deputy Administrator concurs with Judge Tenney's finding that the ''overriding purpose of [the] Respondent's prescribing practices was the treatment of Patient A's pain,'' a legitimate medical purpose. In the balance, the Deputy Administrator finds that it is in the public interest for the Respondent to retain his DEA Certificate of Registration.

However, the Deputy Administrator notes with concern the large quantities of controlled substances prescribed to Patient A over an extended period of time. Yet the conflicting expert opinion evidence presented leads to the conclusion that the medical community has not reached a consensus as to the appropriate level of prescribing of controlled substances in the treatment of chronic pain patients. Given this dispute, the Deputy Administrator is reluctant to conclude that the Respondent's prescribing of controlled substances to Patient A lacked a legitimate medical purpose or was outside the usual course of professional practice. It remains the role of the treating physician to make medical treatment decisions consistent with a medical standard of care and the dictates of the Federal and State law. Here, the preponderance of the evidence established that the Respondent so acted.

Therefore, the Deputy Administrator finds that the public interest is best served by taking no action with respect to the continued registration of the Respondent. Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 21 CFR 0.100(b) and 0.104, hereby orders DEA Certificate of Registration AS7287534, issued to William F. Skinner, M.D., be, and it hereby is, continued, and that any pending applications be, and they hereby are, granted. This order is effective January 8, 1996.

Dated: November 30, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–29770 Filed 12–6–95; 8:45 am]

BILLING CODE 4410–09–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Administration.

ACTION: Notice of availability of proposed records schedules; request for comments.